

Applicant: Zurcher, Robert G.
Application Serial No.: 09/922,620
Filing Date: August 16, 2001
Docket No.: 102-477 CIP (P-3522/1P1)
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Amendments to the Specification:

Please amend the specification to read as follows:

On page 2, please replace paragraph [0004] with the following:

B¹
[0004] As a result, numerous devices have been developed for shielding needles after use. These structures usually involve some sort of shield arrangement, which moves in place over the used needle, once it has been removed from the patient. Current shielding structures for IV infusion or blood collection assemblies are often cumbersome, expensive and complex. In fact, the wings of these assemblies may interfere with the closure of some of the current shielding structures. Additionally, some of the current shielding structures may interfere with the normal and accepted procedure of one handed ~~needle~~ needle placement techniques or are so complex that they preclude use of the device in certain procedures or with certain devices and/or assemblies.

On pages 5 to 6, please replace paragraph [0017] with the following:

B²
[0017] The present invention provides a needle assembly that ~~include~~ includes a safety shield to protect the user from contacting a used needle. Specifically, the present invention provides for ~~a~~ an intravenous (IV) infusion or blood collection assembly having a safety shield. The present invention is extremely easy to use and requires only one-handed operation versus two-handed operation as required by some existing products. The use of this invention is intuitive, so it will not require retraining of users. The needle assembly of the present invention provides for safely handling such devices by reducing exposure to the used needle piece of the assembly as well as reducing the risk of accidental needle sticks while an operator is covering the used needle. Additionally, the present invention provides a safety shield that does not interfere with the wings present on a needle assembly. Thus, the presence of the wings does not inhibit the movement and operation of the safety shield.

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On page 6, please replace paragraph [0018] with the following:

33 [0018] One embodiment of the intravenous (IV) infusion assembly 10 of the present invention is shown in FIGS. 1 and 2. The winged IV infusion assembly 10 of the present invention includes an elongate housing 12, an elongate needle 14 that extends distally from a distal end 12a of ~~12a~~ the housing 12 and a length of tubing 16 that extends proximally from a proximal end 12b of ~~12b~~ the housing 12. The needle 14 and the tubing 16 extend outwardly from the housing 12 and are connected in fluid communication by the housing 12. The housing 12 has a pair of oppositely directed wings 20 and 22 extending outwardly from the housing 12. Housing 12, needle 14 and tubing 16 are of ~~convention~~-conventional constitution and are typically used for blood collection and IV infusion.

On page 6, please replace paragraph [0019] with the following:

[0019] The wings 20 and 22 of the assembly 10 are projected outwardly from the housing 12 and may be flexible or rigid. Generally, the wings 20 and 22 are formed as an integral structure with housing 12 with each wing flexing at the boundary therewith. The wings 20 and 22 may be attached to the distal end 12a or proximal end 12b of the outer sides of the housing 12. Wings 20 and 22 are used in the same way as wings on a conventional IV infusion assembly. Wings 20 and 22 provide the user with better gripping means so that the needle placement is easier. The wings 20 and 22 aid in ~~the~~ positioning the needle at a desirable angle with respect to insertion, which reduces the incidence of penetration of the needle 14 through the far wall of the vein. Additionally, the wings 20 and 22 inhibit the assembly from rotating or moving while the needle 14 is in the patient. Thus, wings 20 and 22 protect the patient from injury that may result from needle movements while the needle is in the patient.

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On page 7, please replace paragraph [0020] with the following:

[0020] Flexible tubing **16** extends from the proximal end **12b** of the housing **12** and, as is conventionally known, is used to allow the user to connect assembly **1610** to supplies of infusion liquids or for the return of collected blood if the arrangement is being used to collect blood.

On page 7, please replace paragraph [0021] with the following:

33
[0021] In order to cover the needle **14** once it has been withdrawn from the patient, the present invention provides a safety shield assembly **40**. Safety shield assembly **40** includes a safety shield **50** and a mounting clip **64** for securing the safety shield to the housing **12**. Safety shield assembly **40** is typically formed of molded plastic and is preferably integrally formed as described in detail hereinbelow. The shield **50** of present invention includes a proximal end **50b**, a distal end **50a**, a pair of opposed sidewalls **52** and **53** and a top surface **58** thereby defining an elongated recess **60** extending from the distal end **50a** to the proximal end **50b** for housing the needle **14** therein.

On page 8, please replace paragraph [0025] with the following:

34
[0025] One sidewall **52** or **53** has an inwardly directed distal protrusion **70** adjacent to the distal end of the shield **50a** that are useful for engaging the needle when the shield is in the closed position. It is also contemplated that more than one distal protrusion **70** may be located on sidewall **52** or **53**. The distal protrusion **70** provides a second locking mechanism to keep the shield **50** in its closed position **80** over the needle **14**. The distal protrusion **70** engages the needle **14** as the shield **50** is moved into position **80** enclosing the needle. The protrusion **70** is ~~deflatably~~ deflectably moved by the needle **14** as the shield **50** is closed over the needle **14**. Once the needle **14** passes the end of the protrusion **70**, the protrusion returns to its original undeflected position and the needle is permanently locked in recess area **60** of the shield **50**.

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On page 8, please replace paragraph [0026] with the following:

35 [0026] Thus, the shield of the present invention locks the needle in the elongate recess by a double locking mechanism which securely and permanently locks the shield over the needle. Alternative locking and closure mechanisms for the protective shield may be used. The locking assemblies desirably provide a secure locking position of the shield relative to the needle so as to prevent a used needle from being exposed against inadvertent tough contact by the user.

On pages 8 to 9, please replace paragraph [0027] with the following:

35 [0027] The shield assembly 40 is mounted to the infusion needle assembly 10 by clip 64. Clip 64 is arranged about wings 20 and 22 adjacent housing 12 and Clip 64 includes two spaced apart clip extensions 64a and 64b which surround wings 20 and 22 adjacent housing 12. The clip extensions 64a and 64b are flexible members, which may be used to snap clip 64 onto housing ~~10~~ 12 in conventional fashion. In that regard, clip ~~extends~~ extensions 64a and 64b each have a living hinge 67 and 68, respectively, which enables them to be positionable about the wings 20 and 22 adjacent to the housing 12. The clip 64 and shield 50 may be integrally formed as a unitary article of manufacture and having a hinge axis 24 ~~therebetween~~ therebetween. Useful types of structures forming hinge axis 24 include mechanical hinges and various linkages, living hinges or combinations of hinges and linkages.

On pages 9 to 10, please replace paragraph [0029] with the following:

35 [0029] Although a living hinge is the preferred hinge mechanism, any type of hinge axis that is capable of moving the shield about the ~~hub~~ housing of the assembly is suitable for use with the present invention. Acceptable hinges include mechanical hinges and various linkages, living hinges or combinations of hinges and linkages. For instance, the shield may be connected to the housing by a hanging bar and hook arm whereby the hanging bar engages with the hook

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B7
arm so that the shield may be pivoted with respect to the collar and the shield is easily movable into several positions. Thus, the shield may be ~~connected to~~ connected to the housing by an interference fit between the hanger bar and the hook arm.

{ On page 10, please replace paragraph [0030] with the following: }

B8
[0030] The needle 14 desirably has an upwardly facing beveled distal end 14a for easy intravenous access. The assemblies of the present invention desirably have the shield 50 and wings 20 and 22 connected in alignment with the upwardly facing bevel end 14a of the needle 14a14. Alignment of the shield 50, wings 20 and 22 and needle 14 with the upwardly facing distal bevel end 14a of the needle 14 makes it easier to insert the needle into the patient and does not require any manipulation of the assembly 10 before use. Additionally, the orientation of the shield 50 and wings 20 and 22 provides a visual indication to the user of the orientation of the bevel end 14a of the needle 14.

On page 10, please replace paragraph [0033] with the following:

B9
[0033] The shield assembly 140 in FIGS. 3 and 4 has its hinge axis 124 on the distal end 112a (or needle side) of the housing 112b112. In this embodiment, the proximal protrusions 172 and 174 engage the housing 112 on the distal end 112a of the housing 112b112. The distal protrusion 170 engages the needle 114 in an identical manner as in the first embodiment shown in FIGS. 1 and 2.

{ On page 11, please replace paragraph [0034] with the following: }

B10
[0034] Safety shield assembly 140 is mounted to the infusion needle ~~assembly~~ assembly 110 by clip 164. Clip 164 includes two spaced apart clip extenders 164a and 164b which surround wings 120 and 122 adjacent to the housing 112. The function of all the other aspects of the safety shield assembly 140 are identical.

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On page 11, please replace paragraph [0038] with the following:

371 [0038] Preferably, the shield and housing are moldable parts which can be mass produced as will be understood, from a variety of materials including, for example, polyethylene, polyvinyl chloride, polystyrene, and the like. Additionally, certain metals may be found to be useful for the shield and housing. Materials are selected which will provide the proper covering and support for the structure of the invention in its use, but which will provide also a degree of resiliency for the purposes of providing the cooperative movement relative to the cooperating abutments of the assembly.

{ On page 12, please replace paragraph [0039] with the following: }

[0039] The shield IV infusion or blood collection assembly of the present invention may be used in a manner similar to standard winged type assemblies. For instance, for IV infusion assemblies, the assembly of the present invention is connected to an IV apparatus and the needle placed in the patient. The safety shield is maintained about the hinge axis towards the proximal side of the assembly so that it does not interfere with the placement of the needle. The wings on either side of the assembly may be used to help position the needle in a desirable angle in the vein. Once the needle is removed, the shield is pivotally moved about the hinge axis toward the distal side of the needle until the shield reaches its permanently locked position. Desirably the shield assembly is moved with one hand, which leaves the user's other hand free.